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U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
NORTHEASTERN DIVISION

ARMOND ROUSE, Plaintiff, v. DEPUY ORTHOPAEDICS, INC., an Indiana corporation; JOHNSON & JOHNSON SERVICES, INC., a New Jersey corporation; Defendants.	)	CASE NO.: _____ **JURY DEMAND** **PLAINTIFF DEMANDS A TRIAL BY STRUCK JURY**

COMPLAINT

COMES NOW the Plaintiff, by and through his undersigned attorneys, and files this Complaint against the Defendants and in support thereof would show as follows:

PARTIES

1. Plaintiff Armond Rouse, is an adult resident of Madison County, Alabama.

2. Defendant, DePuy Orthopaedics, Inc., is an Indiana corporation, with its principal place of business located in Warsaw, Indiana.

3. Defendant, Johnson & Johnson Services, Inc., is a New Jersey corporation, with its principal place of business located in New Brunswick, New Jersey.

VENUE

4. Venue is proper pursuant to 28 U.S.C. §81 and §1391 because a substantial part of the events or omissions giving rise to the claim occurred within the Northern District of Alabama and the injuries at issue in this lawsuit occurred in the Northern District of Alabama.

5. Defendants conduct business in the Northern District of Alabama to include, but not limited to, the sale of hip implant systems.

JURISDICTION

6. The amount in controversy exceeds, exclusive with interest and costs, the sum of $75,000.00. Jurisdiction is appropriate pursuant to 28 U.S.C. §1332 based upon the complete diversity of the parties.

FACTS COMMON TO ALL COUNTS

A. THE DEPUY PINNACLE ® ACETABULAR CUP SYSTEM IS DEFECTIVE, UNSAFE AND HAS NOT BEEN ADEQUATELY TESTED

7. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is often characterized as a ball and socket joint. The acetabulum is the cup shaped socket portion of the hip and the femoral head (ball) at the top of the femur bone rotates within the curved surface of the acetabulum.

8. A total hip system replaces the body's natural joint with an artificial one, usually made out of metal, plastic, or ceramic. A typical hip replacement system consists of four separate components: (1) a femoral stem, (2) a femoral head, (3) a liner (bearing surface), and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the metal femoral stem is implanted. The femoral head is usually a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint that can rotate when it is placed inside a plastic, ceramic, or metal liner that is attached to the interior portion of the metal acetabulum cup (socket) comprised of metal on its outer shell. When complete, the femoral stem anchors the metal femoral head that rotates within the liner sitting inside the acetabular cup.

9. Defendants developed, designed, tested, manufactured, distributed, and sold the Pinnacle® Acetabular Cup System (hereinafter the "Pinnacle Hip") which is a hip bearing system to be used in a total hip replacement or revision surgery. The Pinnacle Hip system includes two component parts: the liner and acetabular cup. Defendants developed, designed, tested, manufactured, and distributed at least four different metal acetabular cups and three different liners to be used as the Pinnacle Hip. The acetabulum cup is comprised of titanium metal on its outer shell and can be fixed to the bone with screws or without screws by growing into the bone with Defendants Gripton™ porous technology. The Pinnacle Hip has three different liners to choose from made of cobalt-chromium metal, polyethylene plastic or ceramic. Defendants have several different cobalt-chromium metal liners that are used in the Pinnacle Hip which include the Pinnacle Metal-On-Metal Acetabular Cup Liner and the Ultamet® XL.

10. The Pinnacle Hip is critically different than most hip replacements since it uses a metal acetabular liner instead of a polyethylene plastic acetabular liner. The Pinnacle Hip with a metal liner, such as the Ultamet® XL, is a "metal-on-metal" device due to the fact that both articulating surfaces - the femoral head (ball) and acetabulum liner (socket) - are comprised of cobalt-chromium (CoCr) metal. Therefore, the metal-on-metal design forces metal to rub against metal with the full weight and pressure of the human body creating metallic debris to be released into the Plaintiff's hip socket and blood stream. Because of Defendants' defective design for the Pinnacle Hip, hundreds of patients--including Plaintiff--have been forced to undergo surgeries to replace the failed hip implants.

11. Defendants describe the Pinnacle Hip as "the only product available that provides the option of choosing a polyethylene or metal insert for use with the same outer titanium cup that replaces the socket of the natural hip."

12. Defendants developed, designed, tested, manufactured, and distributed the metal and ceramic femoral heads that are used with the Pinnacle Hip that directly contact the liner. The Articul/eze-M Spec Femoral Head and the aSphere M-Spec Femoral Head are metal femoral heads commonly used with the Pinnacle Hip.

13. The Pinnacle® Hip is fully compatible with DePuy's complete line of advanced femoral stems that Defendants develop, design, test, manufacture, and distribute such as the AML®, Prodigy®, Summit™, Corail®, Tri-Lock®, and S-ROM femoral stems and sleeves.

14. The Pinnacle Hip is a Class III medical device. Class III devices are those that operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients.

15. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical devices, including the Pinnacle Hip, to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and submit the results of the investigations to the FDA.

16. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties, and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

17. The FDA may grant premarket approval only if it finds that there is reasonable

assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

18. A medical device on the market prior to the effective date of the MDA – a so-called "grandfathered" device – was not required to undergo premarket approval.

19. In addition, a medical device marketed after the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a pre-MDA device (i.e., a device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and simply requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then approve the new device for sale in the United States.

20. The MDA does not require an FDA determination that the device is in fact, substantially equivalent to a grandfathered device.

21. Instead of assuring the safety of the Pinnacle Hip through clinical trials, Defendants sought to market the Pinnacle Hip without conducting any clinical trials by obtaining FDA approval under section 510(k). To that end, Defendants submitted a section 510(k) premarket notification of intent to market the Pinnacle Hip.

22. By telling the FDA that the Pinnacle Hip's design was "substantially equivalent" to other hip components and products on the market, Defendants were able to avoid the safety review required for premarket approval under FDA regulations including clinical trials.

23. The FDA cleared the Pinnacle Hip for sale by means of the abbreviated 510(k) process and consequently the FDA did not require the Pinnacle Hip to undergo clinical trials.

24. The 510(k) notification for the Pinnacle Hip includes Defendants assertion that it

believes the Pinnacle Hip to be substantially equivalent to devices that had never been reviewed for safety and effectiveness.

25. Significantly, unlike the premarket approval process, the 510(k) notification process does not call for scrutiny – or even clinical testing – of a device's safety and effectiveness.

26. A finding of substantial equivalence is not equivalent to a finding of a device's safety and effectiveness.

27. Thus, the FDA's finding of "substantial equivalence" had nothing to do with reviewing the Pinnacle Hip's safety and effectiveness, but rather only a determination of equivalence to devices that they underwent no safety and effectiveness review.

28. Defendants sold approximately 150,000 Pinnacle Hips.

B. DEFENDANTS HAVE CONTINUED TO MARKET THE PINNACLE HIP DESPITE KNOWLEDGE OF PROBLEMS AND OVER 1,300 REPORTED ADVERSE EVENTS.

29. Defendants have received over 1,300 complaints and reports associated with the Pinnacle Hip since it has been on the market, and the number is expected to grow. Had Defendants conducted clinical trials of the Pinnacle Device before it was first released on the market in the early 2000's, they would have discovered at that time what they have ultimately learned - that the Pinnacle Hip results in a high percentage of patients developing pain, metallosis, biologic toxicity and an early and high failure rate due to the release and accumulation of metal particles in the patient's surrounding tissue when there is friction (wear or edge-loading) of the cobalt-chromium metal femoral head that rotates within the cobalt-chromium metal acetabular liner. The metallic particulates released by friction of the metal-on-metal surfaces can become toxic causing metallosis or cobaltism giving rise to pseudotumors or other conditions. The formation of metallosis,

pseudotumors, and infection and inflammation causes severe pain and discomfort, death of surrounding tissue and bone loss, and a lack of mobility.

30. In May 2002, shortly after Defendants began selling the Pinnacle Hip, Defendants received two complaints. One reported that a patient had to undergo revision surgery to remove and replace the Pinnacle Hip because the liner disassociated with the cup and another reported revision surgery because the acetabular cup had loosened. DePuy closed their investigation of the filed complaints finding that "corrective action is not indicated."

31. Since 2002 Defendants have continued to receive hundreds of similar complaints reporting that failure of the Pinnacle Hip (metal-on-metal) that forced patients to undergo painful and risky surgery to remove and replace the failed hip. By the end of 2008, Defendants received more than 400 reports, and by the end of 2009, that number skyrocketed to almost 750.

32. From January 1, 2011 to March 31, 2011, the FDA received over 250 self-reported adverse events regarding the Pinnacle Hip. Reported symptoms range from pain, infection, inflammation, feeling as if dislocating, heavy metal poisoning (metallosis) confirmed by blood tests resulting in eventual revision, ALVAL fluid (Aseptic Lymphocytic Vasculitis Associated Lesion) and necrotic tissue in and around the hip joint, catastrophic failure, premature wear, disarticulation, and disassembly.

33. Consequently, Defendants have been fully aware for years that the Pinnacle Hip was defective and that hundreds of patients had been injured by the Pinnacle Hip causing hundreds of patients to undergo the agony of another surgery, but Defendants continued to market and sell the defective Pinnacle Hip implant despite the knowledge of the Pinnacle Hip's defect. In so doing, Defendants actively concealed the known defect from doctors and patients-- including Plaintiff and his doctor--and misrepresented that the Pinnacle Hip was a safe and effective medical device.

34. Defendants could have either stopped selling the defective implant when it became aware that it had catastrophically failed in patients or provided further warning to medical providers and/or their customers of the unreasonable dangers instead of actively promoting and marketing these hips for installation into patients' bodies.

35. To this day, Defendants continue to sell the defective Pinnacle Hip to unsuspecting patients without any warning about the risks or the failures that have been reported over the years.

36. Defendants tout the metal-on-metal Pinnacle Hip in brochures saying "the DePuy metal-on-metal (MoM) articulation system is leading the way in advanced technology. Through years of careful engineering, research and expertise, we've created a total hip replacement solution that offers low wear and high stability.[1]"

37. Defendants claim "DePuy Orthopaedics remains the leader in metal-on-metal technology, offering several advantages, including larger diameter bearings that can improve hip range of motion and stability. In fact, one study conducted since the device was approved in 2002 observed that an estimated 99.9 percent of Pinnacle Hip components remain in use.[2]" One of the Pinnacle Hip designers William P. Barrett, MD, of Valley Orthopaedic Associates/Proliance Surgeons in Renton, WA has been quoted in Defendants marketing materials saying "the Pinnacle cup exhibited 99% survivorship at five years and, significantly, differences between patients, surgeons, femoral stems, head size, and articulation types did not affect survival."

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[1] "Advancing High Stability and Low Wear" Brochure; The study was presented at the AAOS 2007 Annual Meeting by at least one of the Pinnacle Hip designers, William P. Barrett, (Kirk Kindsfater, William Barrett, James Dowd, Carleton Southworth, Marilyn Cassell. Poster #P077, "Midterm Survival of the Pinnacle Multi-Liner Acetabular Cup in a Prospective Multi Center Study," 2007 AAOS Annual Meeting.)

[2] **http://www.depuy.com/healthcare-professionals/product-details/pinnacle-acetabular-cup-system-48mm-66mm**

38. Defendants advertised that "only Pinnacle Hip Solutions feature TrueGlide™ technology, allowing the body to create a thin film of lubrication between surfaces. The result is a smooth, more fluid range of natural motion." Defendants distributed a press release stating "the aSphere head, combined with DePuy's exclusive TrueGlide technology, facilitates a more fluid range of natural motion and up to 159 degrees range of motion."

39. Defendants advertised that "the Pinnacle™ Acetabular Cup System is DePuy's premium product for acetabular indications and can address all existing pathologies."

40. Defendants advertised that "for the first time surgeons have the choice between high performance bearings which all work within the Pinnacle™ Acetabular Cup System."

41. Other Pinnacle Hip advertisements and brochures included pictures of a man on the beach in wet suit carrying a surf board and a man playing tennis (which specifically describes him as a bilateral replacement). There are pictures of women stretching and engaging in other athletic activities such as riding a bike.

42. Defendants marketed the Pinnacle Hip as high performance hip replacements and as superior products that would allow patients to return to their more active lifestyles. Defendants also advertised the Pinnacle Hip would last longer than other hip replacement products.

43. A number of governmental regulatory agencies have recognized the problems that are caused by metal-on-metal implants such as the Pinnacle Hip. For instance, in April 2010, the Medicines and Healthcare Products Regulatory Agency ("MHRA") in Britain investigated and released a *Medical Device Alert* about Defendants' metal-on-metal total hip replacement system after receiving widespread reports of soft tissue reactions and tumor growth in thousands of patients who had received these implants. MHRA has required physicians to establish a system to closely monitor

patients known to have metal-on-metal hips by monitoring the cobalt and chromium ion levels in their blood and to evaluate them for related soft tissue reactions.

44. Similarly, on May 28, 2010 the Alaska Department of Health issued a bulletin warning of the toxicity of Defendants' metal-on-metal total hip replacement systems. The State of Alaska, like the MHRA, identified the need for close medical monitoring, surveillance and treatment of all patients who had received these and similar metal-on-metal implants.

45. On February 10, 2011 the Food and Drug Administration (FDA) launched a website addressing risks and concerns linked to metal-on-metal hip implants that recommends medical monitoring of these types of patients. The FDA website states that "different people will react to these metal particles in different ways, [and] at this time, it is not possible to know who will experience a reaction, what type of reaction they might have, when the reaction will occur, or how severe the reaction will be. However, it is known that over time, the metal particles around some implants can cause damage to bone and/or tissue surrounding the implant and joint." The website further states "this is sometimes referred to as an "adverse local tissue reaction (ALTR)" or an "adverse reaction to metal debris (ARMD)". Such a reaction may cause the implant to become loose or cause pain. Ultimately this can require a revision surgery where the old device is removed and replaced with another one." The FDA warns that "because the metal ball and the metal cup slide against each other during walking or running, some tiny metal particles may wear off of the device and enter into the space around the implant. Some of the metal ions from the metal implant or from the metal particles may even get into the bloodstream. Orthopaedic surgeons take several precautions before and during the implantation surgery to try to optimize the way in which the ball and socket rub against each other so that fewer wear particles are produced. However, there is no way to fully avoid the production of metal particles."

46. Defendants have known for years that implantation of their Pinnacle Hip and other metal-on-metal total hip replacement systems results in metallosis, biologic toxicity and an early and high failure rate. Once the body is exposed to and absorbs the toxic metallic ions and particulate debris from the Pinnacle Hip, inflammation occurs, causing severe pain, necrosis (death) of the surrounding tissue and bone loss. Pseudotumors also develop and grow as a direct and proximate result of the toxic metallic particles and ions released from the metal-on-metal hip components.

47. According to published medical literature, the only solution for elevated cobalt levels is revision surgery.

C. Plaintiff's Pinnacle Hips ARE Defective and HAVE Failed Causing Him Pain and Suffering, Forcing Him to Suffer Additional Pain

48. Plaintiff is currently sixty-two years old and has a DePuy Pinnacle Hip system.

49. On or about December 14, 2005, Plaintiff underwent left hip replacement surgery at Huntsville Hospital and his surgeon, Dr. Wayne Goodson installed a Pinnacle Hip. Plaintiff has the following implanted component parts: a Pinnacle Sector II Acetabular Cup (64mm), Pinnacle Ultamet Metal Insert (36 mm ID x 64mm OD), Summit Tapered Hip Stem with Porocoat (size 8), and an Articule/eze Metal on Metal Femoral Head (36 mm).

50. The increased presence of said metal ions in the Plaintiff's bloodstream can cause significant health problems, the exacerbation of pre-existing conditions, while subjecting the Plaintiff to increased medical diagnosis and treatments.

51. Had Plaintiff known that the Pinnacle Hip caused the symptoms he is experiencing, and the probable need for revision surgeries, Plaintiff would not have elected the Pinnacle Hip.

52. As a direct and proximate result of the failure of his defective Pinnacle Hip

system, Plaintiff sustained and continues to suffer damages, including, but not limited to, past, present, and future pain and suffering, severe and possibly permanent injuries, emotional distress, disability, disfigurement, economic damages (including medical and hospital expenses) monitoring, rehabilitative and pharmaceutical costs, and lost wages and loss of future earnings capacity. As a result, Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial.

53. Revision surgeries are generally more complex than the original hip replacement surgery, often because there is a reduced amount of bone in which to place the new hip implants. Revision surgeries also usually take longer than the original hip replacement surgery, and the revision surgery has a higher rate of complications. Additionally, if metal particles or metal debris from the Pinnacle Hip are present, the revision surgery is more difficult.

54. Plaintiff will need many years of continuous medical treatment as a direct and proximate cause of the faulty Pinnacle Hip.

55. Plaintiff's injuries may be permanent, and they may cause additional complications in the future including revision surgeries.

56. All of the injuries and complications suffered by Plaintiff were caused by the defective design, warnings, construction and unreasonably dangerous character of the Pinnacle Hip that was implanted in him. Had Defendants not concealed the known defects, the early failure rate, the known complications and the unreasonable risks associated with the use of the Pinnacle Hip, Plaintiff would not have consented to the Pinnacle Hip being used in his total hip arthroplasty.

COUNT ONE

AEMLD

57. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

58. Defendants are liable to the Plaintiff for the damages sustained based on the Alabama Extended Manufacturer's Liability Doctrine (AEMLD) as the Defendants manufactured, designed, or sold a defective product which, because of its unreasonably unsafe condition, injured the Plaintiff when such product, substantially unaltered, was put to its intended use. Furthermore, Defendants failed to adequately warn the Plaintiff of the unreasonably dangerous nature of this product.

WHEREFORE, PREMISES CONSIDERED, Plaintiff demands judgment against the Defendants and any subsequently named Defendants separately and severally, for compensatory and punitive damages as a jury may award. Plaintiff demands such other and further relief as the Court deems proper and just.

COUNT TWO

NEGLIGENCE AND WANTONNESS

59. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

60. Defendants are liable to the Plaintiff for the damages sustained based on common law negligence and/or wantonness.

61. Plaintiff alleges that the acts of the Defendants, when combined together, caused the injuries of the Plaintiff as complained of herein. Plaintiff alleges that the negligent and wanton acts of both Defendants contributed in such a way as to proximately result in the Plaintiff's injuries.

WHEREFORE, PREMISES CONSIDERED, Plaintiff demands judgment against the Defendants and any subsequently named Defendants separately and severally, for compensatory and

punitive damages as a jury may award. Plaintiff demands such other and further relief as the Court deems proper and just.

COUNT THREE

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

62. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

63. Defendants are liable to the Plaintiff for the damages sustained based on a breach of the implied warranty of merchantability.

64. The device was not fit for its ordinary purposes.

65. The Plaintiff was a foreseeable user of the device.

66. The device was being used in the intended manner at the time of the Plaintiff's injury.

67. The Plaintiff suffered harm as a direct and proximate result of the above said defects in the device.

WHEREFORE, PREMISES CONSIDERED, Plaintiff demands judgment against the Defendants and any subsequently named Defendants separately and severally, for compensatory and punitive damages as a jury may award. Plaintiff demands such other and further relief as the Court deems proper and just.

COUNT FOUR

BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

68. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

69. Defendants are liable to the Plaintiff for the damages sustained based on a breach of the implied warranty of fitness for particular purpose.

WHEREFORE, PREMISES CONSIDERED, Plaintiff demands judgment against the Defendants and any subsequently named Defendants separately and severally, for compensatory and punitive damages such as a jury may award. Plaintiff demands such other and further relief as the Court deems proper and just.

COUNT FIVE

BREACH OF EXPRESS WARRANTY

70. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

71. The Defendants made affirmations of fact with respect to the Pinnacle Hip intended to induce the sale of the hip replacement device for implantation into the Plaintiff's body.

72. Such affirmations related to the qualities and characteristics of the Pinnacle Hip regarding its design, manufacture and safety, and the suitability for implantation into the Plaintiff's body.

73. The above said affirmations became part of the basis of the bargain involving the sale of the device for implantation into the Plaintiff's body.

74. The Defendants breached its express warranty relating to the device, in that the above said affirmations were not true.

75. The Plaintiff has suffered harm as a direct and proximate result of the Defendants' breach of express warranty.

WHEREFORE, PREMISES CONSIDERED, Plaintiff demands judgment against the Defendants and any subsequently named Defendants separately and severally, for compensatory and

punitive damages as a jury may award. Plaintiff demands such other and further relief as the Court deems proper and just.

COUNT SIX

FRAUDULENT MISREPRESENTATION

76. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

77. Defendants made fraudulent misrepresentations with respect to the Pinnacle Hip system in the following particulars:

a. Defendants represented through the labeling, advertising, marketing materials, detail persons, seminar presentations, publications, and/or notice letters that the Pinnacle Hip (metal on metal hip system) had been tested and found to be safe and effective for the treatment of pain and inflammation; and

b. Defendants represented that the quality and character of their Pinnacle Hip was safer than other alternative hip devices.

78. Defendants knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risk of the Pinnacle Hip to consumers, including Plaintiff, and the medical community.

80. The representations were made by Defendants with the intent that doctors and patients, including Plaintiff, rely upon them.

81. Defendants' representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of the Pinnacle Hip system.

82. Plaintiff and his physicians did in fact rely upon the representations.

83. Defendants' fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

84. Plaintiff was injured as a direct and proximate result of Defendants' actions, omissions, and misrepresentations. Plaintiff has incurred, and will continue to incur expenses as a result of using the Pinnacle Hip.

85. Defendants acted with oppression, fraud, and malice towards Plaintiff, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake of example and for the purpose of punishing Defendants for their conduct, in an amount sufficiently large to be an example to others, and to deter these Defendants and others from engaging in similar conduct in the future.

WHEREFORE, PREMISES CONSIDERED, Plaintiff demands judgment against the Defendants and any subsequently named Defendants separately and severally, for compensatory and punitive damages as a jury may award. Plaintiff demands such other and further relief as the Court deems proper and just.

COUNT SEVEN

FRAUDULENT CONCEALMENT

86. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

87. Defendants fraudulently concealed information with respect to the Pinnacle Hip system in the following particulars:

a. Defendants represented through the labeling, advertising, marketing materials, detail persons, seminar presentations, publications, and/or notice letters that the Pinnacle Hip was safe and fraudulently withheld and

concealed information about the substantial risks of using the Pinnacle Hip; and

b. Defendants represented that the Pinnacle Hip was safer than other alternative medications and fraudulently concealed information which demonstrated that the Pinnacle Hip was not safer than alternatives available on the market.

88. Defendants had sole access to material facts concerning the dangers and unreasonable risks of the Pinnacle Hip.

89. The concealment of information by Defendants about the risks of the Pinnacle Hip was intentional, and the representations made by Defendants were known by Defendants to be false.

90. The concealment of information and the misrepresentations about the Pinnacle Hip were made by Defendants with the intent that doctors and patients, including Plaintiff, rely upon them.

91. Plaintiff and his physicians relied upon the representations and were unaware of the substantial risks of the Pinnacle Hip which Defendants concealed from the public, including Plaintiff and his physicians.

92. Plaintiff was injured as a direct and proximate result of Defendants' actions, omissions, and misrepresentations. Plaintiff has incurred, and will continue to incur expenses as a result of using the Pinnacle Hip.

93. Defendants acted with oppression, fraud, and malice towards Plaintiff, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake of example and for the purpose of punishing Defendants for their conduct, in an amount sufficiently large to be an example to others, and to deter these Defendants and others from engaging in similar conduct in the future.

WHEREFORE, PREMISES CONSIDERED, Plaintiff demands judgment against the Defendants and any subsequently named Defendants separately and severally, for compensatory and punitive damages as a jury may award. Plaintiff demands such other and further relief as the Court deems proper and just.

COUNT EIGHT

FRAUDULENT INDUCEMENT AND SUPPRESSION

94. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

95. Defendants misrepresented to the Plaintiff and the health care industry the safety and effectiveness of the Pinnacle Hip and/or fraudulently, intentionally and/or negligently concealed material information, including adverse information regarding the safety and effectiveness of the Pinnacle Hip.

96. Defendants made misrepresentations and actively concealed adverse information at a time when the Defendants knew, or should have known, that the Pinnacle Hip had defects, dangers, and characteristics that were other than what the Defendants had represented to the Plaintiff and the health care industry generally. Specifically, Defendants misrepresented to and/or actively concealed from the Plaintiff, the health care industry and consuming public that:

a. Defendants represented through the labeling, advertising, marketing materials, detail persons, seminar presentations, publications, and/or notice letters that Pinnacle Hip had been tested and found to be safe and effective for the treatment of pain and inflammation; and

b. Defendants represented that Pinnacle Hip was safer, in better quality and in character than other alternative hip devices.

97. The misrepresentations of and/or active concealment alleged were perpetuated directly and/or indirectly by Defendants.

98. Defendants knew or should have known that these representations were false and made the representations with the intent or purpose that the Plaintiff and health care industry would rely on them, leading to the use of the Pinnacle Hip.

99. At the time of the Defendants fraudulent suppression, Plaintiff was unaware of the falsity of the statements being made and believed them to be true. Plaintiff had no knowledge of the information concealed and/or suppressed by Defendants.

100. Plaintiff justifiably relied on and/or were induced by the misrepresentations and/or active concealment and relied on the absence of safety information which the Defendants did suppress, conceal or failed to disclose to the Plaintiff's detriment.

101. Defendants had a post-sale duty to warn Plaintiff and the public about the potential risks and complications associated with the Pinnacle Hip in a timely manner.

102. The misrepresentations and active fraudulent concealment by the Defendants constitute a continuing tort against the Plaintiff, who received the Pinnacle Hip.

103. Defendants made the misrepresentations and actively concealed information about the defects and dangers of the Pinnacle Hip with the intention and specific desire that Plaintiff's health care professionals and the consuming public would rely on such or the absence of information in selecting the Pinnacle Hip as medical treatment.

104. As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentation of Defendants, Plaintiff suffered significant and ongoing injury and damages.

WHEREFORE, PREMISES CONSIDERED, Plaintiff requests that the trier of fact render a verdict for the Plaintiff and against the Defendants, jointly and severally, for compensatory

damages in an amount which will adequately compensate Plaintiff for the injuries and damages sustained by him due to the Defendants' conduct; and for exemplary damages in an amount which will adequately reflect the wrongfulness of Defendants' conduct. Further, Plaintiff request that the Court enter judgment consistent with said verdict, and that it also award Plaintiff interest from the date of judgment and the costs incurred by the Court in managing this lawsuit.

DATED this 15th day of March, 2012.

s/Ted L. Mann
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JURY DEMAND

Plaintiff demands a trial by jury.

s/Ted L. Mann
Ted L. Mann

REQUEST FOR SERVICE

Pursuant to FRCP 4.1 and 4.2, Plaintiff requests service of the foregoing Complaint by certified mail.

s/Ted L. Mann

Ted L. Mann

SERVE DEFENDANTS BY CERTIFIED MAIL AS FOLLOWS:

DEPUY ORTHOPAEDICS, INC.
700 Orthopaedic Drive
Warsaw, Indiana 46581

JOHNSON & JOHNSON SERVICES, INC.
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933